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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,119	04/12/2004	Walter Muller	512100-2034	3517

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,119	MULLER, WALTER	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/12/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's IDS filed 04/12/2004.

Claims 1-20 are pending and included in the prosecution.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/835,997 in view of US 6,348,501 ('501). The subject

matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are subject matter as follows: patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent. The claims of the copending application are generic in terms of the active agent.

However, the present claims are different from the copending claims because the copending claims not claiming any specific drugs while the present claims recite capsaicin.

US '501 teaches capsaicin to treat pain administered topically in encapsulated form to reduce the inflammatory effect on capsaicin on the skin (abstract; col.3, lines 13-19; col.4, lines 56-60).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent as claimed by the copending application, and deliver capsaicin disclosed by US '501 in the microreservoirs claimed by the copending application because US '501 teaches that encapsulation of topically applied capsaicin reduces its inflammatory effect on the skin, with reasonable expectation of having patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent to be delivered to the skin without causing any inflammation to the skin at the site of application of the patch.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a question or doubt introduced by the limitations following the expression "preferably" or "such as" because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, claim 1 recites the broad limitation of the therapeutic agent "at least 1%" and recites the

narrower limitations "2%, 3%, and 5%". Claim 4 recites the broad limitation "butanediol" and the narrower limitation "1,3-butanediol". Claim 9 recites broad limitation of the microreservoirs in the matrix "less than 40%" and recites the narrower limitations "lass that 35%", and "between "20 and 30%". Claims 13 and 14 recite the broad limitation "30-200 g/cm^3" and recites the narrower limitations "50-120 g/cm^3".

Additionally, the expression "saturation concentration" in claim 1, and the expressions "high tack" and "low tack" in claim 11 do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions.

6. Claims 17-19 provide for the use of tropical patch, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 17-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-11, 13-14, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,071,657 ('657) in view of US 6,348,501 ('501).

US '657 teaches a device for transdermal administration of active medicinal agent dissolved in a nonflowable gel that form microdispersions (microreservoirs) in a silicone elastomer (abstract). The concentration of the active agent in the microdispersions is from 50-80%, and the total amount of the microdispersions in the adhesive is from 25-75% (col.2, lines 28-36). The microdispersions comprises thickener, i.e. viscosity increasing agent, including cellulose ether and polyacrylic compounds, and solvent (col.2, lines 41-45; col.3, lines 17-22). The solvents include propylene glycol, and diethylene glycol and ethers thereof including ethylene glycol monoethyl ether, which are the amphiphilic solvents claimed by applicant (col.2, lines 53-57). The solvents are sufficiently lipophilic to dissolve the medicine, and on the other hand, are adequately hydrophilic to provide the desired active agent transport through the skin (col.2, lines 46-49). The transdermal device suitable to deliver drugs having low water solubility (col.1, lines 45-55), i.e. lipophilic drugs including analgesics, and capsaicin is lipophilic analgesic drug. The silicone elastomer comprises more than one polysiloxane compounds including polydimethylsiloxane, i.e. amine resistant polysiloxane (col.3, lines 55-67). The reference discloses nominal method of making the device including mixing the ingredients and forming a silicone layer having thickness of

0.5-5mm (col.4, lines 44-52). The device has a backing layer and protective film (col.5, lines 36-45).

Although US '657 teaches suitability of the disclosed transdermal system to deliver analgesics and lipophilic drugs, however, US '657 does not explicitly teach capsaicin as an active agent to be delivered by the device.

US '501 teaches capsaicin to treat pain administered topically in encapsulated form to reduce the inflammatory effect on capsaicin on the skin (abstract; col.3, lines 13-19; col.4, lines 56-60). Capsaicin is known to treat neuropathic.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polysiloxane layer containing microdispersions comprising a lipophilic active agent in an amphiphilic solvent as disclosed by US '657, and deliver lipophilic capsaicin disclosed by US '501 in the microdispersions of US '657 because US '501 teaches that encapsulation of topically applied capsaicin reduces its inflammatory effect on the skin, with reasonable expectation of having transdermal device comprising polysiloxane layer containing microdispersions comprising capsaicin in an amphiphilic solvent to be delivered to the skin without causing any inflammation to the skin at the site of application of the device.

The combination of the references does not teach the coating weight of the drug containing adhesive on the backing layer as claimed by claims 13 and 14. However, such coating weight does not impart patentability of the claims in absence of superior and unexpected results obtained from this coating weight.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '657 and US '501, and further in view of US 7,247,315 ('315).

The combined teachings of US '657 and US '501 are previously discussed as set forth on this office action.

Although the combined teachings of US '657 and US '501 teach polysiloxane adhesive polymers, however, does not teach silicone oil in the adhesive composition.

US '315 teaches transdermal delivery patch comprising drug matrix layer comprising polydimethylsiloxane and dimethicone (silicone oil) in an amount of 4-7% that acts as plasticizer for the polydimethylsiloxane and such an amount has as drug flux rate lowering effect providing more predictable and uniform flux rate of the drug through the skin (abstract; col.3, lines 21-25, 32-33, 39-45).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polysiloxane layer containing microdispersions comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '657 and US '501, and further add 4-7% silicone oil to the matrix layer as disclosed by US '315 because US '315 teaches that 4-7% dimethicone when added to polydimethylsiloxane acts as plasticizer for the polydimethylsiloxane and has as drug flux rate lowering effect providing more predictable and uniform flux rate of the drug through the skin, with reasonable expectation of having transdermal device comprising polysiloxane layer containing microdispersions comprising a capsaicin in an amphiphilic solvent and further

comprising 4-7% silicone oil wherein the flux rate of capsaicin delivery through the skin is predictable and uniform.

10. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '657 and US '501, and further in view of US 5,494,680 ('680).

The combined teachings of US '657 and US '501 are previously discussed as set forth on this office action.

Although the combined teachings of US '657 and US '501 teach backing material, however, does not teach the specific backing materials as claimed by claims 15 and 16, or the thickness of the backing as claimed by claim 15.

US '680 teaches transdermal delivery device having backing that is flexible such that the device conforms to the skin. The material of the backing can be polyester or ethylene vinyl acetate copolymer (col.4, line 60 till col.5, line 1).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising backing layer and polysiloxane layer containing microdispersions comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '657 and US '501, and select the backing material from polyester or ethylene vinyl acetate copolymer as disclosed by US '680, because US '680 teaches backing made of such material is flexible such that the device conforms to the skin, with reasonable expectation of having transdermal device comprising backing layer of polyester or ethylene vinyl acetate copolymer and

polysiloxane layer containing microdispersions comprising a capsaicin in an amphiphilic solvent wherein the device is flexible and conforms to the skin, therefore comfortable to the user.

The thickness of the backing material as claimed by claim 15 does not impart patentability to the claims absent unexpected results obtained from such a thickness.

11. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '657 and US '501, and further in view of US 6,239,680 ('180).

The combined teachings of US '657 and US '501 are previously discussed as set forth on this office action.

Although the combined teachings of US '657 and US '501 teach analgesic effect of capsaicin, however, the combination of the references does not explicitly teach treatment of neuropathic pain as claimed by claims 17-19.

US '180 teaches that capsaicin and its analog are extremely effective therapy for treating neuropathic pain (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polysiloxane layer containing microdispersions comprising capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '657 and US '501, and use the patch to treat neuropathic pain as disclosed by US '180, because US '180 disclosed that capsaicin and its analog are extremely effective therapy for treating neuropathic pain, with reasonable expectation of having transdermal device comprising polysiloxane layer

containing microdispersions comprising a capsaicin in an amphiphilic solvent that treat neuropathic pain effectively.

12. Claims 1-11, 13-20 are rejected under 35 U.S.C. 103(a) as being obvious over US 2004/0202710 ('710) in view of US '501.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US '710 teaches transdermal therapeutic system comprising matrix comprising amine resistant polysiloxane polymer and microreservoirs containing lipophilic active substance and amphiphilic solvent (abstract; paragraphs 0014, 0038). The active

substances included analgesics (paragraph 0047). The amphiphilic solvents include butanediol, such as 1,3-butanediol, dipropylene glycol, tetrahydrofurfuryl alcohol, diethylene glycol dimethyl ether, diethylene glycol monoethyl ether (paragraph 0025). The microreservoirs contain 50-80% solvent, therefore, 20-50% active substance (paragraph 0019), And the microreservoirs forms 20-30% of the polysiloxane as implied teaching of paragraph 0017 that polysiloxane forms 70-80% of the matrix. The microreservoirs further comprises cellulose derivatives or high molecular weight polyacrylic acid as thickeners (paragraph 0033). The system comprising backing layer of polyester or ethylene vinyl acetate copolymer (paragraph 0042).

The teachings of US '501 are discussed previously as set forth on this office action.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising an active agent in an amphiphilic solvent as disclosed by US '710, and deliver capsaicin disclosed by US '501 in the microreservoirs disclosed by US '710 because US '501 teaches that encapsulation of topically applied capsaicin reduces its inflammatory effect on the skin, with reasonable expectation of having patch comprising self adhesive polysiloxane matrix containing microreservoirs comprising capsaicin in an amphiphilic solvent to be delivered to the skin without causing any inflammation to the skin at the site of application of the patch.

The combination of the references does not teach the coating weight of the drug containing adhesive on the backing layer as claimed by claims 13 and 14 or the

thickness of the polyester backing as claimed by claim 15. However, such coating weight and backing thickness do not impart patentability of the claims in absence of superior and unexpected results obtained from these parameters.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '710 and US '501, and further in view of US 7,247,315 ('315).

The combined teachings of US '710 and US '501 are previously discussed as set forth on this office action.

Although the combined teachings of US '710 and US '501 teach polysiloxane adhesive polymers, however, does not teach silicone oil in the adhesive composition.

The teachings of US '315 are previously discussed as set forth in this office action.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polysiloxane layer containing microreservoirs comprising a capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '710 and US '501, and further add 4-7% silicone oil to the matrix layer as disclosed by US '315 because US '315 teaches that 4-7% dimethicone when added to polydimethylsiloxane acts as plasticizer for the polydimethylsiloxane and has as drug flux rate lowering effect providing more predictable and uniform flux rate of the drug through the skin, with reasonable expectation of having transdermal device comprising polysiloxane layer containing microreservoirs comprising a capsaicin in an amphiphilic solvent and further comprising

4-7% silicone oil wherein the flux rate of capsaicin delivery through the skin is predictable and uniform.

14. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '710 and US '501, and further in view of US 6,239,680 ('180).

The combined teachings of US '710 and US '501 are previously discussed as set forth on this office action.

Although the combined teachings of US '710 and US '501 teach analgesic effect of capsaicin, however, the combination of the references does not explicitly teach treatment of neuropathic pain as claimed by claims 17-19.

The teachings of US '180 are previously discussed as set forth in this office action.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal device comprising polysiloxane layer containing microreservoirs comprising a capsaicin in an amphiphilic solvent as disclosed by the combined teachings of US '710 and US '501, and use the patch to treat neuropathic pain as disclosed by US '180, because US '180 disclosed that capsaicin and its analog are extremely effective therapy for treating neuropathic pain, with reasonable expectation of having transdermal device comprising polysiloxane layer containing microreservoirs comprising a capsaicin in an amphiphilic solvent that treat neuropathic pain effectively.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 7,063,860 teaches that capsaicin is a lipophilic drug used to treat neuropathic pain, and can be administered transdermally (col.5, lines 15-20, 34-43; col.22, line 25).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali

ISIS GHALI
PRIMARY EXAMINER